DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/9/2009 has been entered.

Any previous rejection not reiterated has been withdrawn due to claim amendments. Note that the previous rejection under 35 U.S.C. 102(b) using US Patent 5948682 should have been under 35 U.S.C. 102(e). Any inconvenience is regretted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moloney (WO/ 9621029, relying on US Patent 5650554) and Friman et al (1994).

Moloney discloses a method in preparing heterologous proteins, including bioactive peptides on oil bodies (see title and abstract). More specifically, the method includes producing polypeptides fused to oil body proteins, like oleosins (see Abstract) using plant cells as the host (see column 4). The following recitation with respect to the chimera DNA sequence is made in column 4: "In particular, the present invention provides a method for the expression of a recombinant polypeptide by a host cell said method comprising: a) introducing into a host cell a chimeric DNA sequence comprising: 1) a first DNA sequence capable of regulating the transcription in said host cell of 2) a second DNA sequence, wherein said second sequence encodes a recombinant fusion polypeptide and comprises (i) a DNA sequence encoding a sufficient portion of an oil body protein gene to provide targeting of the recombinant fusion polypeptide to a lipid phase linked in reading frame to (ii) a DNA sequence encoding said recombinant polypeptide; and 3) a third DNA sequence encoding a termination region functional

in the host cell; and b) growing said host cell to produce the recombinant fusion polypeptide." Regarding heterologous proteins, Moloney makes the following recitation in columns 16-17: "Of particular interest are those proteins or peptides that may have a therapeutic or diagnostic value. These proteins include antigens, such as viral coat proteins or microbial cell wall or toxin proteins or various other antigenic peptides, peptides of direct therapeutic value such as interleukin-1-.beta., the anticoagulant hirudin, blood clotting factors and bactericidal peptides, antibodies, specifically a single-chain antibody comprising a translational fusion of the VH or VL chains of an immunoglobulin. Human growth hormone may also be produced. The invention is not limited by the source or the use of the recombinant polypeptide."

With respect to step (d) of claim 1, the instant specification defines the term "washing the oil bodies" as any process that removes cellular contaminants or undesirable properties and such methods may include separation methods such as centrifugation (paragraph 55). This prior art reference provides methods for the separation of heterologous proteins from host cell components by partitioning of the oil body fraction (see claim 2). Lastly, the authors provide that such a formulation may be added into animal feeds (see column 16). This meets the limitation of administering the formulation to an animal by way of oral administration. Because, this reference provides

the same steps, the same results are expected to occur (i.e. an immune response would be elicited).

Friman discloses methods of vaccination by way of oral administration of antigen. The authors disclose that such a method lead to strong immune responses, including specific IgG antibody-secreting cells responses (see whole document, Abstract).

Thus it would have been obvious to one of ordinary skill in the art to combine the teachings above in order to perform the claimed method. One would have been motivated to do so given the success taught by Friman in evoking strong immune responses. There would have been a reasonable expectation of success given the methods are well described in the prior art. The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5948682 (Moloney) and Friman et al (1994).

Moloney discloses a method in preparing heterologous proteins on oil bodies (see title and abstract). More specifically, the method includes producing polypeptides fused to oil body proteins, like oleosins, (see columns 30-37, Examples 7-14) in various plant species, including safflower (see column 38, Example 16). The following recitation with respect to the chimera DNA sequence is made : "The present invention also provides a chimeric DNA sequence encoding a fusion polypeptide, capable of being expressed in association with an oil body of a host cell comprising: 1) a first DNA sequence

capable of regulating the transcription in said host cell of 2) a second DNA sequence, wherein said second sequence encodes a fusion polypeptide and comprises (i) a DNA sequence encoding a sufficient portion of an oil body protein gene to provide targeting of the fusion polypeptide to a lipid phase linked in reading frame to (ii) a DNA sequence encoding a heterologous polypeptide; and 3) a third DNA sequence encoding a termination region functional in the host cell." Regarding heterologous proteins, Moloney makes the following recitation in column 18, paragraph 4: "Of particular interest are those proteins or peptides that may have a therapeutic or diagnostic value. These proteins include antigens, such as viral coat proteins or microbial cell wall or toxin proteins or various other antigenic peptides, peptides of direct therapeutic value such as interleukin-1-.beta., the anticoagulant hirudin, blood clotting factors and bactericidal peptides, antibodies, specifically a single-chain antibody comprising a translational fusion of the VH or VL chains of an immunoglobulin. Human growth hormone may also be produced. The invention is not limited by the source or the use of the heterologous polypeptide."

With respect to step (d) of claim 1, the instant specification defines the term "washing the oil bodies" as any process that removes cellular contaminants or undesirable properties and such methods may include separation methods such as

centrifugation (paragraph 55). This prior art reference provides methods for the separation of heterologous proteins from host cell components by partitioning of the oil body fraction (see column 7, paragraph 3). Column 18 provides that the formulation may be added to animal feeds and thus meet the limitation of administering the formulation. Because the prior art provides the same steps, the same results are expected to occur (i.e. an immune response is elicited).

Friman discloses methods of vaccination by way of oral administration of antigen. The authors disclose that such a method lead to strong immune responses, including specific IgG antibody-secreting cells responses (see whole document, Abstract).

Thus it would have been obvious to one of ordinary skill in the art to combine the teachings above in order to perform the claimed method. One would have been motivated to do so given the success taught by Friman in evoking strong immune responses. There would have been a reasonable expectation of success given the methods are well described in the prior art. The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are rejected on the ground of nonstatutory double patenting over claims 10-12 of U. S. Patent No. 6761914 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the same method, the same steps and the same formulation administered. The method, steps and formulation that are claimed by both sets comprise the following: a method of eliciting an immune response by administering a formulation to an animal comprising an antigen and washed oil bodies.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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